Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Scheme of Teaching and Examination

Master of Pharmacy (M. Pharmacy)

(Industrial Pharmacy)

II – Semester

S. No.	Board of Study	Subject Code	Subject Name	Periods per week			Scheme of Examination			Total Marks	Credit L+(T+P)/2
							Theory/Practical				
				L	T	P	ESE	CT	TA		
1	Pharmacy	501211 (41)	**Industrial Pharmacy** – I (Pharmaceutical Production & Management)	4	1	-	100	20	20	140	
2	Pharmacy	501212 (41)	**Industrial Pharmacy** – II (Pharmaceuticals Regulatory Affairs)	4	1	-	100	20	20	140	
3	Pharmacy	501213 (41)	**Industrial Pharmacy** – III (Biopharmaceutics and Clinical Research)	4	1	-	100	20	20	140	
4	Pharmacy	501214 (41)	**Industrial Pharmacy** – IV (Controlled and Novel Drug Delivery)	4	1	-	100	20	20	140	
5	Pharmacy	501221 (41)	**Industrial Pharmacy** – I (Pharmaceutical Production & Management) Lab	-	-	6	100	-	40	140	
6	Pharmacy	501222 (41)	**Industrial Pharmacy** – II (Biopharmaceutics and Clinical Research) Lab	-	-	6	100	-	50	150	
7	Pharmacy	501223 (41)	**Industrial Pharmacy** – III (Controlled and Novel Drug Delivery) Lab	-		6	100	-	50	150	
Total				**16**	**4**	**18**	**700**	**80**	**220**	**1000**	

L- Lecture, T- Tutorial, P- Practical,

Duration of Theory paper 3 hours

ESE – End Semester Examination, CT – Class Test, TA- Teacher Assessment

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester**: M. Pharmacy 2nd semester** Branch: **Pharmacy**
Subject: **Industrial Pharmacy** – I (Pharmaceutical Production & Management) Subject Code: **501211 (41)**
Total Theory Periods: **40** Total Tutorial Periods: **12**
Total Marks in the End Semester: **100**
Minimum of Class Tests to be Conducted: **02**

UNIT- I

Current Good Manufacturing Practices: Manufacturing facilities for tablets, capsule, liquid orals, semisolids and parenterals as per schedule M. Procedure for GMP Certification for pharmaceutical industries. WHO GMP minimum document check list, schedule U. Brief study of Master Formula Records as per WHO, GMP,ANVISA,ICH, USFDA,TGA,MHRA. Quality Audit.

UNIT -II

Production, planning, control and documentation: production scheduling, forecasting , vendor development, capacity assessment (plant, machines, human resources), production management, production organization, objectives and policies. Productivity, management and cost controls.

UNIT -III

Inventory Management: Costs in inventory, inventory categories – special considerations, selective inventory control, reorder quantity methods and Economic order quantity, EOQ, inventory models, safety stock- stock out, lead time – reorder time methods, modern inventory management systems, inventory evaluation.

UNIT -IV

Material Management and Maintenance. Store management, salvaging disposal of scrap and surplus. Materials – quality and quantity, value analysis, purchasing- centralized and decentralized, vendor development, buying techniques, purchasing cycle and procedures. Classification of maintenance-corrective (break-down) maintenance, and preventive maintenance, predictive maintenance, scheduled maintenance.

UNIT -V

Pricing of products. Cost of imports, material cost, direct labor cost, over-heads, unit cost, profit other marketing expenditures, MRP. Classification of products according to DPCO.

Recommended Books.

- Forensic Pharmacy by B.S. Kuchekar, A. M. Khadatare and S. C. Jitkar, 6th Ed., Nirali Prakashan.
- Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi.
- James Swarbrick, James C Boylon, Encyclopedia of Pharmaceutical Technology, 2nd Ed. Marcel Dekker Inc.
- Gnarino Richard A, New Drug Approval Process, 3rd Edition, Marcel Dekker Inc.
- P. Warayan, Intellectual Property Laws, Eastern Law House.
- Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
- Pharmacy Law and Ethics by Dale and Appelbes, the Pharmaceutical Press, Joy Winfield.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester**: M. Pharmacy 2nd semester** Branch: **Pharmacy**
Subject: **Industrial Pharmacy – II** (Pharmaceuticals Regulatory Affairs) Subject Code: **501212 (41)**
Total Tutorial Periods: **12** Total Theory Periods: **40**
Total Marks in the End Semester: **100**
Minimum of Class Tests to be Conducted: **02**

Unit I.

ISO 9000 and 14000, validation, ICH and eCTD. Salient features of Total Quality Management. Role of production departments in implementation and documentations.

Unit II

Intellectual property rights. Patent procedures. Salient features of GATT, TRIPS, TRIMS & CRAMPS.

Unit III

DRA. Procedures for obtaining licenses of direct manufacturing, contract manufacturing, import, export, sales and distribution of drugs and formulations.

Unit IV

Industrial hazards, safety, pollution control and effluent treatment. Introduction, Factory act and rules, Fundamentals of accident prevention, elements of safety programme, electrical hazards, chemical hazards, gas hazards.

Unit V

Pilot plant and scale up techniques: Significance, pilot study of some important dosage forms such as tablets, capsules and liquids orals, discussion on important parameters such as formula , equipments , product uniformity and stability, raw material process and physical layouts, personal requirements and reporting responsibilities.

Recommended Books.

- The internal quality audit by Monica Girmaldi and Janet Gough Davis Harwood International Publishing.
- Statistical Design and Analysis in Pharmaceutical Science, by Chow, (Marcel Dekker).
- Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
- Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
- Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
- Bubuarm N.R, Whatever one should know about patent, 2nd Ed., Pharma Book Syndicate.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M. Pharmacy 2nd semester** Branch: **Pharmacy**
Subject: **Industrial Pharmacy** – III (Biopharmaceutics and Clinical Research) Subject Code: **501213 (41)**
Total Theory Periods: **40** Total Tutorial Periods: **12**
Total Marks in the End Semester: **100**
Minimum of Class Tests to be Conducted: **02**

UNIT -I

Absorption of drugs. Mechanisms and factors affecting the gastrointestinal absorption of drugs. Absorption of drugs through sites other than GIT. Distribution of drugs: Drug Disposition and Action, volume of distribution, kinetics of protein binding, Factors influencing distribution of drugs.

UNIT -II

Compare and contrast the effects of various routes of drug administration on the onset, intensity, and duration of pharmacologic effect. Biotransformation of drugs and factors influencing biotransformation.
Elimination and clearance concept: Elimination of drugs and elimination kinetics, Renal clearance, Hepatic clearance.

UNIT-III

Compartment concept: One compartment open model, Multicompartmental models, Model-independent pharmacokinetics. Kinetic of Intravenous IV bolus, Infusion.

UNIT-IV

Formulation characteristics influence the disposition and action of drugs after various routes of administration. Bioavailability and bioequivalence studies. Comparative clinical studies.

UNIT-V

Types of clinical Research procedures, Phases of clinical study, regulation related to uses of animals and human volunteers.

Recommended Books:

- Essentials of **Biopharmaceutics** & **Pharmacokinetics** by Ashutosh Kar.
- **Biopharmaceutics** & **Pharmacokinetics** a Treatise by Brahmankar.
- Principles And Applications Of Biopharmaceutics and Pharmacokinetics: Tippin and Bajaj.
- Applied Biopharmaceutics and kinetics: L eon Shargel, Susanna Wu-Pong, Andrew Yu: McGraw Hill.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester **: M. Pharmacy 2nd semester** Branch: **Pharmacy**
Subject : **Industrial Pharmacy** – IV (Controlled and Novel Drug Delivery) Subject Code: **501214 (41)**
Total Theory Periods: **40** Total Tutorial Periods: **12**
Total Marks in the End Semester: **100**
Minimum of Class Tests to be Conducted: **02**

Unit I

Controlled release oral drug delivery systems.

Fundamental aspects of **Controlled and sustained release:** Combination of dissolution and diffusion controlled, osmotic pressure controlled, pH controlled, ion exchange controlled systems, applications of biodegradable and non biodegradable polymers. Methods of manufacturing and evaluation.

Unit II

Mucoadhesive drug delivery systems.

Structure of oral mucosa and transmucosal permeability, permeability enhancers. In-vitro and in-vivo methods for buccal absorption. Methods of manufacturing and evaluation.

Unit III

Transdermal drug delivery system.

Permeation mechanism, factors affecting permeation through skin. Permeation enhancers. Methods of manufacturing and evaluation of TDDS.

Unit IV

Targeted Drug Delivery Systems

Concept, advantages and disadvantages. Processes involved in manufacturing of nanoparticles, neosomes, liposomes, resealed erythrocytes, microspheres and methods available for evaluation.

Unit V

Ocular Drug Delivery systems.

Fundamental aspects and different approaches for ocular delivery drugs. Fabrication and evaluation of occuserts, eye lenses, in-situ gel. Formulation and evaluation of controlled release ocular drug delivery systems.

Recommended Books:

- Controlled Drug Delivery System, J.R. Robinson and V.H.S.L. Lee.
- The theory and practice of Industrial pharmacy, III rd edition, L. Lachman, H. A. Liberman.
- Modern Pharmaceutics, II nd edition, G. S. Banker, C.T. Rhodes.
- Controlled and Novel drug delivery: R.K. Khar and S.P.Vyas,IInd edit.
- Latest International and National journals of Pharmacy and Technology.

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Semester**: M. Pharmacy 2nd semester** Branch: **Pharmacy**

Subject: **Industrial Pharmacy** – I (Pharmaceutical Production & Management) Lab Subject Code: **501221 (41)**

Total Practical Periods: **72**

Total Marks in the End Semester: **100**

Practicals:

- Preparation of Master Formula of tablet, granules, capsules and interpretation.
- Preparation of Master Formula of granules and interpretation.
- Preparation of Master Formula of capsules and interpretation.
- Preparation of Master Formula of liquid oral and interpretation.
- Preparation of Master Formula of topical liquid and interpretation.
- Preparation of Master Formula of parenteral and interpretation.
- Preparation of Batch Manufacturing Record.
- Preparation of documents related to GMP Certification.
- Preparation of documents related to pricing of product.
- Preparation of documents related to Quality Audit.

Semester: M. Pharmacy. 2nd Semester Branch: **Pharmacy**

Subject : Industrial Pharmacy – II (Biopharmaceutics and Clinical Research) Lab Code: **501222 (41)**

Total Practical Periods: **72**

Total Marks in the End Semester: **100**

Practicals:

- Design of different absorption kinetic model for various formulations .
- To study the absorption kinetics from oral route (at least 2 experiments).
- To study the elimination rate kinetics of orally administered drug(at least 2 experiments).
- To study and calculate the protein binding property of different drugs(at least 2 experiments).
- Estimation of drug permeability through various *In-vitro*-models (at least 2 experiments).
- Determination of partition coefficient and effect of pH on partition coefficient.
- Dissolution studies on marketed enteric coated tablets (at least 2 experiments).
- Evaluation of pharmacodynamics of antihypertensive drugs.

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Semester: M. Pharmacy 2nd Semester Branch: **Pharmacy**
Subject: Industrial Pharmacy – III (Controlled and Novel Drug Delivery) Lab Code: **501223 (41)**
Total Practical Periods: **72**
Total Marks in the End Semester: **100**

Practicals:

- To study physicochemical parameters of various polymers.
- To prepare and evaluate diffusion controlled device.
- To prepare and evaluate osmotic controlled device.
- To prepare oral mucoadhesive formulation and evaluation.
- To prepare transmucosal formulation and evaluate for *ex-vivo* permeability.
- To prepare hydro dynamically balanced system and characterization.
- To prepare microsphere and evaluate for its parameters.
- To design and evaluate *in-situ* gel system.
- To prepare and evaluate Transdermal system containing low mol.wt.drug.
- To prepare and characterize liposome of some potent drugs.
- To prepare and characterize Neosome formulations.